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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,754	07/02/2003	Lennart Olsson	REC-104/US	6457
30869	7590	03/10/2005	EXAMINER	
LUMEN INTELLECTUAL PROPERTY SERVICES, INC. 2345 YALE STREET, 2ND FLOOR PALO ALTO, CA 94306			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER

1654

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/613,754

Applicant(s)

OLSSON ET AL.

Examiner

Andrew D Kosar

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14,25-33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 14,25 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13,26,27,33 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 15-24, and 34 have been cancelled by amendment, filed November 12, 2004, and a supplemental reply on January 5, 2005 is acknowledged.

**Claims 1-14, 25-33, and 35 are pending.**

#### ***Election/Restrictions***

Applicant's election with traverse of **Group I** in the reply filed on November 12, 2004, and a supplemental reply on January 5, 2005 is acknowledged. The traversal is on the ground(s) that administration of PKC inhibitors is speculative, and without certainty, for modulation of EPOR. Applicant further asserts that the focus should be on small molecules that modulate by directly binding in to the EPOR. Applicant has not provided evidence to rebut the *prima facie* case. However, in response to Applicant's assertion that the focus should be on the small molecule interaction, one could administer PAMAM-HMB or any of compounds 1-5 to modulate EPOR (SA Qureshi, et al. PNAS (1999) 96, 12156-12161).

The requirement is still deemed proper and is therefore made FINAL.

Applicant elected the species of claim 35 for examination, readable upon claims 1-3, 33, and 35.

**Claims 14, 25, and 28-32 are withdrawn** from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed November 12, 2004, and a supplemental reply on January 5, 2005.

**Claims 1-13, 26, 27, 33, and 35 have been examined on the merits.**

The elected species has been found to be free of the prior art.

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The Examiner expanded the search to encompass generic compounds related to the elected species, specifically claim 33, and claim 1 as it reads upon the genus of diazolohehexahydroxyquinoline compounds in combination with the modulating sequence of EPOR.

The genus of diazolohehexahydroxyquinoline compounds in combination with the modulating sequence of EPOR of formula (4) has been found to be free of the prior art.

The Examiner extended the search to the genus of formulae (1), (2), and (3).

The combinations have been found to be free of the prior art.

The following is a statement of reasons for the indication of allowable subject matter: The prior art does not teach or suggest, alone or in combination, a combination comprising the modulating sequence of EPOR and a compound of any of formulae (1)-(4).

Boger and Goldberg (Bioorg. Med. Chem. (2001) 9, 557-562); DM Wojchowski, et al. (Exp. Cell Res. (1999) 253, 143-156); Qureshi, et al. (Proc. Natl. Acad. Sci USA (1999) 96, 12156-12161); and Tilbrook and Klinken (Intl. J. Biochem. Cell Biol. (1999) 31, 1001-1005) provide teachings on EPOR, EPO, and the state of the art with regards to EPO mimetic compounds and EPOR agonists/antagonists. They do not teach or suggest the instant compounds of formulae (1)-(4) in combination with EPOR.

US Patents 4,546,104 and 5,942,520 teach compounds related compounds, but do not teach or suggest, alone or in combination, any of the instantly claimed compounds of formulae (1)-(4) in combination with EPOR.

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***Specification***

The disclosure is objected to because of the following informalities:

The specification recites “\_g” throughout the specification. However, it appears that Applicant intended “μg”, which finds support from extrapolation of the data and/or examples presented.

The specification recites “19xx” as the year of a Prior Art reference, e.g.- paragraphs [0006] and [0008], which should be a specific calendar year.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-13, 26, 27, 33, and 35** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “(4) diazolo-hexahydroxyquinoline” with moiety definitions for Y and various R groups. It is unclear whether Applicant intends the compound structure of paragraph [0054] from the specification, and claim 33, or another structure. Because Applicant does not show a structure in the claim for the descriptive text of the moieties, the claim is unclear.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1-13, 26, 27, 33, and 35** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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The claims, as instantly drafted read upon the person who is administered the various compounds, as the 'combination' can be made by administration of the compound to a person, and EPOR is ubiquitous in the human body. In order to overcome this rejection, Applicant may identify the combination as, e.g.- 'isolated' or 'purified'.

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

**Claims 1-13, 26, and 27** are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-13, 16, and 17 of copending Application No. 10/612,885.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 1-13, 26, 27, 33, and 35** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14, and 16-26 of copending Application No. 10/612,885. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds embraced by the claims and methods of '885 are of the same scope as the compounds of the instant claims. The compounds used in the method of '885 are either anticipated by, or anticipate, the claims of the instant application.


This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Andrew D. Kosar, Ph.D.  
Patent Examiner  
Art Unit 1654

  
**BRUCE R. CAMPBELL, PH.D**  
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